

temperature-controlled fluid, an outer tube shorter than said central tube and surrounding a part of said central tube to form a helical passageway for said physiological fluid between said central and outer tubes, and first and second end caps, each of said end caps having a first part extending axially along an outer surface of said outer tube and being sealed and secured to said outer surface and a second part sealingly engaging said central tube to ensure maintenance of sterility during operation, said second part comprising an elongate cylindrical opening engaging an outer surface of said central tube and extending away from said first part and wherein said central tube extends beyond each of said second parts and forms two elongate connections for being slidably received in respective elongate recesses.

**Remarks**

This Preliminary Amendment is being submitted in conjunction with the filing of the missing parts of the application.

To overcome the rejection of claims 1-21 under 35 USC 251, being submitted herewith is a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1).

In submitting the reissue specification in double column format as required under 37 CFR 1.173(a)(1), the applicant has included the claims as amended in the previous parent applications, so as not to cause any additional unnecessary confusion.

The hereto amended claim 15, however, includes both the minor amendment effected in the previous parent applications and amendments made subsequent to the Office Action dated December 5, 2000 in parent application 08/758,853.

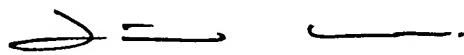
In particular, claim 15 has been amended to recite a helical passageway formed between the central tube and the outer tube whereby the physiological fluid passes. By having a helical passageway, the physiological fluid is passed smoothly from one end of

the heat exchanger to the other end, while being heated by the surface of the continuous helical groove formed on the exterior of the central tube.

In contrast, the Thermodynnetics reference discloses an inner tube 10 formed with a series of annular corrugations 12 that is covered by an outer tube 20. As best shown in Figs. 1 and 2 and disclosed on page 9, lines 15-17, the ridges 14 of inner tube 10 have a diameter that is less than the diameter of passage 21. In other words, there is no contact between ridges 14 of inner tube 10 and the inner surface of outer tube 30. As a consequence, the fluid that passes between the space separated by inner tube 10 and outer tube 20 is met by the series of corrugations 12 so that turbulence is created for the passing fluid. In the case of flowing blood, such turbulence tends to have an adverse effect. Indeed, this is acknowledged by Thermodynnetics in the embodiment shown in Fig. 4. For the Fig. 4 embodiment, the inner tube 410, which is in corrugated form, is helically wound about a center body 440 so as to restrict the flow of blood in a parallel fashion across the various coils from inlet port 432 to outlet port 434. Fig. 5 is a cross-sectional view of Fig. 4 that shows a number of openings 430 in a parallel fashion to guide the passage of blood, in contrast to the heat exchanger of the instant invention whose helical path allows a smooth continuous flow of the being temperature regulated fluid from the inlet port to the outlet port.

In view of the foregoing, applicant respectfully submits that claims 15-18 each are patentably distinguishable over the prior art.

Respectfully submitted,



Louis Woo, Reg. No. 31,730  
Law Offices of Louis Woo  
1901 N. Fort Myer Drive, Suite 501  
Arlington, Virginia 22209  
Phone: (703) 522-8872

Date: 7/15/02

**VERSION TO SHOW MARKINGS TO SHOW CHANGES MADE**

**Attachment Specification Portions Pursuant to 37 C.F.R. 1.121(b)(1)(iii)**

Page 1, before the first paragraph, insert the following paragraph:

This application is a continuation of application No. 08/758,853 filed December 2, 1996, since abandoned, which is a continuation of application No. 08/571,706 filed December 6, 1995, since abandoned, which is a continuation of application No. 08/145,099 filed November 3, 1993, since abandoned, which is a continuation of application No. 07/979,434 filed November 20, 1992, since abandoned, which is a continuation of application No. 07/558,177 filed July 26, 1990, since abandoned, which is a reissue of application No. 06/866,910 filed May 27, 1986, patent No. 4,759,749.

**Attachment Claims Pursuant to 37 C.F.R. 1.121(c)(1)(ii)**

Please amend claim 15 as follows:

15. (Twice Amended) A sterile heat exchanger for controlling the temperature of a physiological fluid comprising a central tube having high heat conductivity for carrying a temperature-controlled fluid, an outer tube shorter than said central tube and surrounding a part of said central tube to form a helical passageway for said physiological fluid between said central and outer tubes, and first and second end caps, each of said end caps having a first part extending axially along an outer surface of said outer tube and being sealed and secured to said outer surface and a second part sealingly engaging said [inner] central tube to ensure maintenance of sterility during operation, said second part comprising an elongate cylindrical opening engaging an outer surface of said central tube and extending away from said first part and wherein said [inner] central tube extends beyond each of said second parts and forms two

2  
a<sub>2</sub>  
60<sub>1</sub>. elongate connections for being slidingly received in [an] respective elongate [recess]  
recesses.